AFFIDAVIT OF DR. MICHAELA ALMGREN

I. Background and Qualifications

1. My name is Michaela Almgren, Pharm.D., M.S. I am over the age of eighteen and competent to testify to the truth of the matters contained herein. The factual statements I make here are true and correct to the best of my knowledge.

2. I am a Clinical Associate Professor in the Department of Clinical Pharmacy and Outcomes Sciences at the University of South Carolina College of Pharmacy. I teach principles of sterile compounding per United States Pharmacopeia ("USP")[1] Chapters 797 and 800, aseptic technique and pharmacy regulations applicable in sterile compounding environment[2] under 503a guidance and section 503b of the Drug Quality and Security Act of 2013, as well as pharmacokinetics, pharmacotherapy, pharmacy law, and biopharmaceutics courses. I specialize in sterile compounding, medication safety and pharmacy laws and regulations that relate to pharmacy compounding practices. I also provide continuing education courses for pharmacists in those topics. I received my Doctor of Pharmacy degree from the University of South Carolina College of Pharmacy in 2010. Additionally, I have a Master's Degree in Pharmaceutical Chemistry from the University of Florida.

3. In conjunction with my academic appointment, I currently maintain a practice site at a 503b[3] outsourcing pharmacy where I perform duties of an outsourcing pharmacist, clinical

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[1] USP sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements in the United States. The USP publishes the United States Pharmacopeia-National Formulary (USP-NF), which contains a compendium of quality standards and specifications for a wide range of pharmaceuticals and related products. USP Chapters 797 and 800 are part of the USP-NF compendium.

[2] Aseptic technique in drug compounding refers to specific practices to avoid physical and microbial contamination when preparing sterile medications that are to be used for parenteral applications, such as IV infusion, injection, etc.

[3] 503b Outsourcing Pharmacy is a compounding pharmacy that produces large batches of sterile products and distributes them directly to health systems pharmacies to address drug shortages, as specified in Section 503B of the FD&C Act.

advisor and pharmacy student preceptor. Previously, I worked in pharmacy operations at a large local teaching hospital as a pharmacist. I have over fifteen years of experience in sterile compounding and aseptic technique. Prior to joining the faculty at the University of South Carolina I worked for several years in pharmaceutical manufacturing where I was involved in drug formulation, quality assurance, quality control and analytical method development and validation. My professional qualifications are Doctor of Pharmacy and Master of Science in Pharmacy with focus on Pharmaceutical Chemistry. A copy of my CV is attached as Exhibit A.

4. I have been asked by attorneys who represent Khalil Allah (or Freddie Owens) whether the August 28, 2024, affidavit provided by the director of the South Carolina Department of Corrections contains adequate information to assess the quality and reliability of the lethal injection drugs the department has obtained for use in his execution, which is scheduled for September 20, 2024. In my expert scientific and pharmaceutical opinion, it does not.

5. The director's affidavit does not provide the date when the drugs were tested. The affidavit also does not include the drugs' "Beyond Use Date," or BUD. BUD refers to the date after which a compounded preparation should not be used, as it may no longer be effective or safe. You need to know these facts to know that the drugs will still be effective on September 20, when the department intends to use them. This is particularly important because the affidavit makes no reference to a Certificate of Analysis from the manufacturer, which suggests to me that the drugs were compounded, not manufactured. Manufactured drugs have a Certificate of Analysis that includes the drug's expiration date. This differs from the BUD, as the expiration date is determined by the manufacturer. The expiration date for commercially manufactured drugs is generally much longer than the BUD for a compounded drug. Commercially manufactured drugs undergo rigorous stability testing under controlled conditions to establish their expiration dates, which can extend

for years. In contrast, compounded drugs are typically made in smaller batches and do not go through the same level of testing, so their stability over time is less certain. Even if a compounded drug passes all USP-required quality tests today, it is still important to know its BUD to ensure that the testing accurately reflects the drug's properties on September 20, provided that the BUD extends beyond that date.

6. The affidavit describes reports the director received from SLED personnel concerning the testing of the drugs. The statement "…acknowledged the substance's concentration in terms of its purity and stability" lacks clarity. The affidavit does not specify the test methods used, the testing procedures followed, or the actual results obtained from those tests. This information is vital to assessing the quality and reliability of the drugs. You would need to know that the SLED laboratory followed all established steps for pharmaceutical drug quality analysis as specified in the USP compendium, which usually differ from typical forensic practice. Documentation of test method validation, calibration curves, details of quality control procedures and methodology used should all be available for review as these are all standard records produced during this type of laboratory analysis. The easiest way to address this concern would be to share the actual analytical reports from the testing of the drugs.

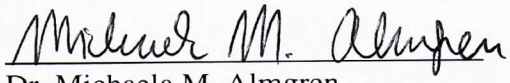
7. The affidavit does not address where the drugs will be stored and how the storage conditions will be monitored between now and September 20th. The nearly three weeks leading up to September 20 provides ample opportunity for quality issues to arise with these drugs if they are not stored correctly, as medications—especially compounded drugs—are sensitive to moisture, light, and temperature. Generally, drugs degrade more rapidly when stored outside their recommended temperature and humidity range. However, simple measures can be implemented to assure that the drug quality is preserved. According to USP Chapter 659 titled "Packaging

Temperature and Storage Requirements", room temperature is generally defined as a range of 20°C to 25°C (68°F to 77°F). This range allows for a variability of 2°C (4°F) above or below the specified range, meaning that the temperature could be between 15°C and 30°C (59°F and 86°F) and still be considered acceptable for room temperature storage. The acceptable humidity level for a pharmacy typically falls within the range of 30% to 60% relative humidity. Pentobarbital sodium injection drug vials should be stored in the conditions described above, as defined by the USP. According to USP Chapter 1079 titled "Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products", storage temperature of medications should be checked daily. Without daily monitoring, temperature excursions may occur, leading to reduced potency and effectiveness of the drug. Once daily temperature measurements should be recorded to document that medications are stored under optimal conditions, safeguarding their quality and effectiveness while complying with regulatory requirements.

8. If the department's drugs degraded, or if their testing was improperly conducted or incomplete, they would pose serious risks to Mr. Allah. As I detailed in my earlier affidavit to this Court, if the drug has an improper pH, it could cause extensive damage to the blood vessels and surrounding tissue. If the drug falls out of solution, the resulting solids, or precipitates, would cause intense pain upon injection. If the potency of the drug is insufficient, the injection could result in a prisoner regaining consciousness, perhaps with organ or brain damage from the oxygen deficits suffered during the attempt at execution.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 31st day of August, 2024.



Dr. Michaela M. Almgren

Acknowledgment Notary Certificate (Only for use in AR, AZ, CO, CT, DC, DE, GA, ID, IA, IL, KS, KY, MA, MD, ME, MN, MO, MT, NH, NJ, NM, NY, NV, NC, OH, OK, OR, PA, RI, SC, TX, UT, VA, WA)

Document Name: Affidavit of Dr. Michaela Almgren

STATE OF South Carolina
COUNTY OF Lexington
(County where notarization occurred)

This record was acknowledged before me on 31 day of August, 2024, by _____ (name(s) of signer(s)), who personally appeared before me and (is personally known to me or whose identity was proved on the basis of satisfactory evidence) to be the person whose name is subscribed to in this document.

KENNETH R. BERG
Notary Public - State of South Carolina
My Commission Expires June 26, 2028

_____ *(Signature of notary public)*

Kenneth R. Berg, Notary Public
(Name of notary public)

My commission expires: 26 June 2028

Official Seal

Personally known _____ OR
Produced identification ✓ Type of identification produced: SCDL